Abstract Title: Mobile electronic solution for clinical research source documentation
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Describe the background of the problem:
As trial complexity increases, there is a growing need to facilitate rapid communication of trial data among the research and clinical care teams. Timeliness of investigator review and high quality data are critical to clinical trial documentation. At Princess Margaret (PM) trials are managed by a team: Investigators, clinical research nurse coordinator (CRNC) for the patient visits and source documentation, study coordinator for the regulatory and data requirements, and correlative staff. Due to program size, staff are in multiple physical locations. Historically PM used standardized paper research charts; however the physical layout of our teams yielded challenges, as only a single team member could utilize the chart at any one time, increasing complexity of achieving data locks, and Investigator review.

Provide metrics or goals hoped to be achieved with the solutions to address the problem:
The goal of the project was to facilitate the workflow of multi-person teams, to enable our Investigators to review/sign off events electronically, and to develop a system to track and review source documentation.

Describe the solutions or methods implemented:
PM developed an electronic application, eSource, which is integrated into the electronic patient record (EPR), allows source documentation into the EPR from a tablet at the point of care, allows for electronic review and approval by Investigators, and enables review of source documentation practices.

Focus groups were held to evaluate application and device needs. Device needs were: usability, compatibility with EPR, and encryption. Application needs were templates for: the informed consent process, clinical notes, vital signs, baseline symptoms, adverse events, and concomitant medications. The project started with a 4 month pilot with 10 CRNCs, and implementation was completed in August 2014 to all our CRNCs.

Describe the outcome of the solutions implemented or show data representing a change whether positive or negative:
eSource currently supports over 70 CRNCs and PM has trained almost 200 Investigators/Fellows on the application. Historically, Investigators were required to review and sign off events within a cycle (~28 days), and there was no capability to determine the total number of events that occurred across trials. In 2015 PM recorded 13,946 adverse events, across 1072 trial patients. The time to review by Investigators was 7.6 days (average). 79% of all adverse events reported were CTCAE grade 1-2. eSource has also enabled systemic reviews of documentation quality, such as reviewing our CRNC practices with completing adverse event attributions, which has driven education and process change.
Show lessons learned, others to involve in the future, changes to the methods to achieve a better outcome:
Point of care electronic documentation was a significant practice change for our CRNCs and Investigators, and change management strategies were required to assist with the adoption of the application, including education about incorporating technology into patient care, and focus groups to identify additional improvements to the IT interface, which are in progress. We are currently assessing new templates to better meet the needs of the research teams. We are also in the process of understanding and exploring the potential for the data in the system, such as systemic reviews of adverse event data by drug class. eSource has been fully implemented for over a year, and following the change management initiatives, the CRNCs have embraced the application, along with the other team members.